ANALGESIC BALM- menthol 10%, methyl salicylate 15% cream Geri-Care Pharmaceuticals, Corp

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

GERI-CARE Analgesic Balm

Drug Facts

Active Ingredient

Menthol 10%

Active Ingredient

Methyl Salicylate 15%

Topical Analgesic

For the temporary relief of minor aches and pains of muscles and joints associated with simple backache, arthritis, strains, bruises and sprains

Warnings

For external use only

Do not use:

- On wounds or damaged, broken or irritated skin
- On a child under 12 years of age with arthritis-like conditions
- With a heating pad

Ask a doctor before use if you have redness over the affected area.

When using this product

- Avoid contact with eyes or mucous membrane
- Do not bandage tightly

Stop Use and ask a doctor

- Conditions worsens or does not improve within 7 days
- Symptoms clear up and occur again within a few days
- Excessive skin irritation develops

Keep out of the reach of Children

If swallowed, get medical help or contact a Poison Control Center immediately

Directions

• Adults and children 12 years of age or older. Apply to the affected area not more than 3 to 4 times daily.

Children under 12 years of age. consult a doctor

• Unless treating hands, wash hands thoroughly with soap and water immediately after use.

Other Information

• Store at controlled room temperature 20°-25°C (68°-77°F)

Questions ? Call 1-800-540-3765

Inactive Ingredients

Carbomer 940, Cetyl alcohol, Glycerol, Glyceryl monostearate, Methylparaben, Polysorbate 80, Propylparaben, Purified Water, Stearic acid, Trolamine

Distributed By

GeriCare Pharmaceuticals 1650 63rd Street Brooklyn, NY 11204 Product of China

Packaging

OUTER BOX



INNER TUBE



ANALGESIC BALM

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57896-116		
Route of Administration	TOPICAL				

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	10 g in 100 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	15 g in 100 g

Inactive Ingredients		
Ingredient Name	Strength	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)		
TROLAMINE (UNII: 903K93S3TK)		
CARBOMER 940 (UNII: 4Q93RCW27E)		
CETYL ALCOHOL (UNII: 936JST6JCN)		
GLYCERYL MONOSTEARATE (UNII: 230 OU9 XXE4)		
METHYLPARABEN (UNII: A218 C7H19 T)		
WATER (UNII: 059QF0KO0R)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
GLYCERIN (UNII: PDC6A3C0OX)		
PROPYLPARABEN (UNII: Z8IX2SC1OH)		

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:57896-116-01	1 in 1 BOX	08/05/2020		
1	28 g in 1 TUBE; Type 0: Not a Combination Product			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph not final	part348	08/05/2020		

Labeler - Geri-Care Pharmaceuticals, Corp (611196254)

Registrant - Trifecta Pharmaceuticals USA LLC. (079424163)

Revised: 7/2020 Geri-Care Pharmaceuticals, Corp